DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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August 27, 2002

WARNING LETTER NO. 2002-NOL-42

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Ronald E. Brumley, President
Bayou State Wholesale Seafood, Inc.
3114 West Old Spanish Trail
New Iberia, Louisiana 70560

Dear Mr. Brumley:

We inspected your firm, located at 520 Burma Road, Ball, Louisiana, on July 26, 2002, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your pasteurized canned crabmeat, refrigerated crabmeat, and crawfish tail meat to be adulterated, pursuant to Section 402(a)(4) and therefore in violation of Section 301(k) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for pasteurized canned crabmeat to control the food safety hazard of *Clostridium botulinum* toxin formation. In addition, your firm does not have a HACCP plan for fresh, refrigerated crawfish tail meat to control pathogen growth and toxin formation.

- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving, storage, and distribution critical control points for the presence of ice to control pathogen growth and toxin formation listed in your HACCP plan for fresh crabmeat.

  The investigator noted that your firm is monitoring the cooler temperature at the storage critical control points for all of your products. However, your firm's HACCP plan lists monitoring the presence of ice as the critical limit at the storage critical control point in all of your HACCP plans. Your HACCP plans should reflect the steps you actually are taking.

If you choose to list cooler temperature instead of adequacy of ice, you must list this in your HACCP plan, keep adequate records of the monitoring activity, and take appropriate corrective actions if monitoring reveals that a critical limit has been compromised. The cooler temperature should be monitored on a continuous basis. Continuous temperature monitoring requires the installation of a temperature recording device to provide monitoring records of the cooler's temperatures during non-business hours, holidays, and weekends.

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh crabmeat lists "cooler temperature not to exceed 45F" at the cooler storage and distribution critical control points. The temperature at those critical control points is not adequate to control pathogen growth and toxin formation.

- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh crabmeat lists checking the level of ice surrounding the product at the cooler storage critical control point is not adequate to control pathogen growth and toxin formation. For example, the temperature of the cooler containing cans of pasteurized canned crabmeat without ice was observed to be approximately 48°F at 10:30 a.m. and 51°F at 1:30 p.m., respectively, during the inspection.

Failure to promptly correct these violations may result in regulatory action by FDA without further notice. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies, and to assure that such violations will not recur. You may wish to include in your response documentation such as your revised HACCP plans, copies of temperature monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practices regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483

cc: Gary M. Kilgo, Manager
Bayou State Wholesale Seafood, Inc.
520 Burma Road
Ball, Louisiana 71405